## PATENT COOPERATION TREAT

## **PCT**

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

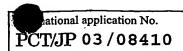
Applicant's or agent's file reference  FOR FURTHER ACTION  See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)				ional Preliminary 416)	
International application No. PCT/JP 03/08410  International filing date (decomposition)  O2.07.2		/month/year)	Priority date (day/month/ye	ear) -	
International Patent Classification (IPC) Int.Cl 7 A61K 31/58, 47/	or national classification and		•	·	
Applicant ALTANA Pharma AG					
This international preliminary e     and is transmitted to the applica	xamination report has been print according to Article 36.	repared by this Int	ernational Preliminary Exam	ining Authority	
2. This REPORT consists of a tot	al of 3 sheets,	including this cov	er sheet.		
This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).					
These annexes consist of a total of sheets.					
3. This report contains indications	3. This report contains indications relating to the following items:				
I Basis of the report					
· II Priority	II Priority				
III Non-establishment	of opinion with regard to nov	velty, inventive st	ep and industrial applicability	•	
IV Lack of unity of invention					
Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement					
VI Certain documents cited					
VII Certain defects in the international application					
VIII Certain observations on the international application					
		•			
Date of submission of the demand		Date of completion	on of this report		
30.01.20	04		26.10.2004		
Name and mailing address of the IPEA/JP		Authorized office		4C 9261	
Japan Patent O	ffice	YUMIKO YAHARA			
3-4-3, Kasumigaseki, Chiyoda-ku,	Гокуо 100-8915, Japan	Telephone No. +81-3-3581-1101 Ext. 3451			



- 1	
1	national application No.
i	PCT/JP 03/08410

I.	Ba	asis of the report	
1.	Wit	th regard to the elements of the international application:*	
	V	the international application as originally filed	•
		the description:	,
		pages	
		pages	, filed with the demand
		pages, filed wit	h the letter of
		the claims:	
·		Nos, as amend	
		Nos, as amend	ed (together with any statement) under Article 19
		Nos, filed with	h the letter of
		the drawings:	·
	Ш	sheets/figs	as originally filed
		sheets/figs	
		sheets/figs, filed with	the letter of
		the sequence listing part of the description:	
		pages	, as originally filed
		pages	, filed with the demand
		pages, filed with	the letter of
	the i	h regard to the language, all the elements marked above were available or funinternational application was filed, unless otherwise indicated under this item se elements were available or furnished to this Authority in the following lang the language of a translation furnished for the purposes of international sear the language of publication of the international application (under Rule 48.2 the language of the translation furnished for the purposes of international por 55.3).	which is: ch (under Rule 23.1(b)).
3.	With exam	n regard to any nucleotide and/or amino acid sequence disclosed in the intern nination was carried out on the basis of the sequence listing:	ational application, the international preliminary
		contained in the international application in written form.	
		filed together with the international application in computer readable form.	
		furnished subsequently to this Authority in written form.	
•		furnished subsequently to this Authority in computer readable form.	
	Ш	The statement that the subsequently furnished written sequence listing international application as filed has been furnished.	ng does not go beyond the disclosure in the
٠		The statement that the information recorded in computer readable form been furnished.	is identical to the written sequence listing has
4.		The amendments have resulted in the cancellation of:	
		the description, pages	
		the claims, Nos.	•
		the drawings, sheets/figs	
5. [		This report has been established as if (some of) the amendments had not bee beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 7	en made, since they have been considered to go 0.2(c)).**
	uus n	acement sheets which have been furnished to the receiving Office in response to report as "originally filed" and are not annexed to this report since they do no	t contain amendments (Rules 70.16 and 70.17)
**	Any r	replacement sheet containing such amendments must be referred to under iten	a 1 and annexed to this report.
			•





<b>V.</b>	Reasoned statement under Artic citations and explanations supp		regard to novelty, inventive step or indu atement	ustrial applicability;
1.	Statement	•		
	Novelty (N)	Claims	1-7	YES
		Claims		NO
	Inventive step (IS)	Claims		YES
		Claims	1-7	NO
	. Industrial applicability (IA)	Claims	1-7	YES
	1	' Claims		NO
	•			

2. Citations and explanations (Rule 70.7)

D1:WO 01/28563 A D2:JP 62-192322 A

The subject matter of claims 1-7 does not involve an inventive step over D1 and D2. D1 discloses aqueous pharmaceutical composition containing ciclesonide and hydroxypropylmethylcellulose 2910, wherein the ciclesonide is dispersed in an aqueous medium in the form of solid particles. D1 also indicates that hydroxypropylmethylcellulose 2910 not only avoids the variations in the concentrations of cicresonide but also may function as stabilizer of the compositions. On the other hands, D2 mentions that autoclaving contributes to the sterilization of aqueous suspension of pregnanolone, a kind of steroids, which has an acetal moiety on its 17 position without any defradation.

Sterilization of the composition is not specifically mentioned in D1, however, considering that a sterilized medicament is implicitly required in this technical field, a skilled person in the art would easily apply sterilization method mentioned in D2 to the ciclesonide-containing composition disclosed in D1.